SUMMARY OF SAFETY AND EFFECTIVENESS	
SPONSOR	Ascension Orthopedics, Inc. A wholly owned division of Integra LifeSciences, Inc. 8700 Cameron Road Austin, TX 78754-3832
510(k) CONTACT:	Susan Walton susan.walton@integralife.com Phone: (512) 836-5001 x1591 FAX (512) 836-6933
DATE PREPARED:	February 12, 2013
TRADE NAME:	Integra Proximal Humeral Fracture Plate System
COMMON NAME:	Plate, Fixation, Bone
CLASSIFICATION:	21 CFR 888.3030 – Single/Multiple component metallic bone fixation appliances and accessories
PRODUCT CODE:	HRS
PANEL:	Orthopedic
PREDICATE DEVICE:	K011815 – Synthes LCP Proximal Humerus Plate K010700 – ATLAS Humeral Plate System
DEVICE DESCRIPTION:	The Integra Proximal Humeral Fracture Plate System is composed of left and right humeral reconstruction plate implants in two options, GT Plate and LP Plate. The GT plate is designed to cover the greater tuberosity and is available in four-hole , seven-hole, and ten-hole lengths or sizes. The LP plate is designed to sit lower on the greater tuberosity and is available in three-hole, six-hole, and nine-hole lengths or sizes. The system features 3.5mm locking, non-locking and lag screws, in addition to, 2.7mm locking screws. The Integra Proximal Humeral Fracture Plate System is a single component made from stainless steel (SS 316L). The non-locking, locking and lag screws are made from stainless steel (SS 316L).
INTENDED USE:	The Integra Proximal Humeral Fracture Plate system is designed for fractures and fracture dislocations, osteotomies and non-unions of the proximal humerus. Indications include: • Dislocated two-, three-, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone • Pseudoarthroses in the proximal humerus • Osteotomies in the proximal humerus
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The technological characteristics for the Integra Proximal Humeral Fracture Plate System were compared to the predicate devices. The characteristics were defined to be device material, dimensional characteristics such as plate length, number and
	location of holes as well as screw sizes and packaging/sterilization

	methods. These characteristics were determined to be the same or similar between the subject and predicate devices.
NONCLINICAL TESTING	The subject system was determined to be equivalent to the predicate devices by comparing the section moduli of the original design (K110700), the subject devices, and the predicate devices (Synthes LCP, K011815). Because the designs included in this 510(k) do not represent a worst case plate, additional testing was not required.
CLINICAL PERFORMANCE DATA:	Clinical performance data were not necessary to support substantial equivalence.
BASIS OF SUBSTANTIAL EQUIVALENCE:	Ascension Orthopedics believes that this system is substantially equivalent to the legally marketed predicate devices based on similarities in design, materials and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ascension Orthopedics, Incorporated
% Ms. Susan Walton
Director
8700 Cameron Road
Austin, Texas 78754

Letter dated: February 13, 2013

Re: K121826
Trade/Device Name: Integra Proximal Humeral Fracture Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: HRS
Dated: January 31, 2013
Received: February 6, 2013

Dear Ms. Walton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use Statement

510(K) Number: K121826

Device Name: Integra Proximal Humeral Fracture Plate System

Indications for Use:

The Integra Proximal Humeral Fracture Plate System is designed for fractures and fracture dislocations, osteotomies and non-unions of the proximal humerus. Indications include:

- Dislocated two-, three-, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone
- Pseudoarthroses in the proximal humerus
- Osteotomies in the proximal humerus

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens

Division of Orthopedic Devices